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February 6, 2003

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: BOX DD, Commissioner for Patents, Washington, DC 20231, on the date below:	
February 6, 2003	
Date	Mark B. Wilson

## BOX DD

Commissioner for Patents  
Washington, DC 20231

RE: *U.S. Patent Application No. 10/043,877 entitled "ANTIHELMINTHIC DRUGS AS A TREATMENT FOR HYPERPROLIFERATIVE DISEASES" – Tapas Mukhopadhyay et al.*  
*Our reference: INRP:095US*  
*Client reference: MDA99-067*

Sir:

Enclosed for filing in the above-referenced patent application is a Supplemental Information Disclosure Statement, Form PTO-1449, and references A1-A8, B3, C28-C49.

No fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:095US.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Steven L. Highlander  
Reg. No. 37,642

REG. 37,259  
For

SLH/cmb  
Encl.: as noted  
25256440.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Tapas Mukhopadhyay *et al.*

Serial No.: 10/043,877

Filed: January 9, 2002

For: ANTIHELMINTHIC DRUGS AS A  
TREATMENT FOR  
HYPERPROLIFERATIVE DISEASES

Group Art Unit: 1641

Examiner: Unknown

Atty. Dkt. No.: INRP:095US

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**BOX DD**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Supplemental Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:095US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

 REG. NO.  
37,259

Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

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Form PTO-1449 (modified)

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List of Patents and Publications for Applicant's

Applicant

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INFORMATION DISCLOSURE STATEMENT

Filing Date:

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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,767,138	6/16/98	Camden	514	365	12/20/96
	A2	5,880,144	3/9/99	Camden	514	397	9/6/97
	A3	5,900,429	5/4/99	Camden	514	395	1/28/97
	A4	5,929,099	7/27/99	Camden	514	365	7/15/96
	A5	6,077,862	6/20/00	Camden	514	388	3/1/99
	A6	6,380,232 B1	4/30/02	Quada, Jr. <i>et al.</i>	514	388	9/26/00
	A7	6,407,131 B1	6/18/02	Quada, Jr. <i>et al.</i>	514	395	9/29/00
	A8	6,420,411 B1	7/16/02	Camden <i>et al.</i>	514	395	9/29/00

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B3	WO 00/41669	7/20/00	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C28	Albonico <i>et al.</i> , "Control strategies for human intestinal nematode infections," <i>Adv. Parasitol.</i> , 42:277-341, 1999.
	C29	Braithwaite <i>et al.</i> , "Clinical pharmacokinetics of high dose mebendazole in patients treated for cystic hydatid disease," <i>Eur. J. Clin Pharmacol.</i> , 22:161-169, 1982.
	C30	Braithwaite <i>et al.</i> , "Cyst and host tissue concentrations of mebendazole in patients undergoing surgery for hydatid disease," <i>The Medical J. of Australia</i> , 2:383-384, 1983.
	C31	Bryceson <i>et al.</i> , "Bioavailability and tolerability of mebendazole in patients with inoperable hydatid disease," <i>Trans. of the Royal Soc. Of Tropical Med. And Hygiene</i> , 76:563-564, 1982.
	C32	Burgat-Sacaze <i>et al.</i> , "Bound residues of veterinary drugs: bioavailability and toxicological implications," <i>Ann. Rech. Vet.</i> , 13:277-289, 1981.

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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C33	Chiba <i>et al.</i> , "Improvement of dissolution and bioavailability for mebendazole, an agent for human echinococcosis, by preparing solid dispersion with polyethylene glycol," <i>Chem. Pharm. Bull.</i> , 39(8):2158-2160, 1991.
	C34	Dawson and Watson, "The effect of dose form on the bioavailability of mebendazole in man," <i>Br. J. Clin. Pharmac.</i> , 19:87-90, 1985.
	C35	Dawson <i>et al.</i> , "The pharmacokinetics and bioavailability of mebendazole in man: a pilot study using [ <sup>3</sup> H]-mebendazole," <i>Br. J. Clin. Pharmac.</i> , 14:453-455, 1982.
	C36	Delatour and Richard, "Embryogenic and antimitotic properties of benzimidazole series," <i>Therapie</i> , 31:505-515, 1976, with English translation.
	C37	Delatour <i>et al.</i> , "Embryotoxic and antimitotic properties of parbendazole, mebendazole and cambendazole," <i>C R Acad Sci Hebd Seances Acad Sci D</i> , 282(5):517-518, 1976, with English translation.
	C38	Description of Vermox® (mebendazole), pp. 1442 From <i>Physicians' Desk Reference</i> , Janssen Pharmaceutica, c1998.
	C39	Edwards and Breckenridge, "Clinical pharmacokinetics of anthelmintic drugs," <i>Clin. Pharmacokinet.</i> , 15:67-93, 1988.
	C40	Elhajouji <i>et al.</i> , "Indication for thresholds of chromosome non-disjunction versus chromosome lagging induced by spindle inhibitors in vitro in human lymphocytes," <i>Mutagenesis</i> , 12:133-140, 1997.
	C41	Farghali and Masek, "Immunopharmacologic agents in the amelioration of hepatic injuries," <i>International J. of Immunopharmacology</i> , 20:125-139, 1998.
	C42	Galtier <i>et al.</i> , "Fasciola hepatica: mebendazole and thiabendazole pharmacokinetics in sheep," <i>Exp. Parasitology</i> , 79:166-176, 1994.
	C43	Kromer, "Similarities and differences in the properties of substituted benzimidazoles: a comparison between pantoprazole and related compounds," <i>Digestion</i> , 56:443-454, 1995.
	C44	Lapras and Delatour, "Antimitotic properties of some embryotoxic and teratogenic anthelmintics derived from benzimidazole," <i>Proceedings of the European Society of Toxicology</i> , 18:294-296, 1977, with English translation.

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Other Art

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C45	Lubega and Prichard, "Interaction of benzimidazole anthelmintics with Haemonchus contortus tubulin: binding affinity and anthelmintic efficacy," <i>Exp. Parasitol.</i> , 73:203-213, 1991.
	C46	Lubega and Prichard, "Specific interaction of benzimidazole anthelmintics with tubulin from developing stages of thiabendazole-susceptible and resistant Haemonchus contortus," <i>Biochem. Pharmacol.</i> , 41:93-101, 1991.
	C47	Michiels <i>et al.</i> , "The pharmacokinetics of mebendazole and flubendazole in animals and man," <i>Arch. Int. Pharmacodyn.</i> , 256:180-191, 1982.
	C48	Upton, "Pharmacokinetic interactions between theophylline and other medication (Part I)," <i>Clin. Pharmacokinet.</i> , 20:66-80, 1991.
	C49	Van Hummelen <i>et al.</i> , "Clastogenic and aneugenic effects of three benzimidazole derivatives in the in vitro micronucleus test using human lymphocytes," <i>Mutagenesis</i> , 10:23-29, 1995.

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